

CETA APPLICATION GUIDE (CAG) ABSTRACTS

AS OF APRIL 2025

CAG-001 - CETA Applications Guide for the use of Compounding Aseptic Isolators in Compounding Sterile Preparations in Healthcare facilities

REVISED 2008

The introduction of USP Chapter 797 in January 2004 (revised in June 2008) along with increased pressure from some State Boards of Pharmacy has led to more robust implementation of environmental controls by facilities involved in the compounding of sterile preparations. In some cases, isolators intended for compounding sterile preparations are used either as an alternative or as an adjunct to traditional methods. Isolator use for sterile compounding is relatively new to the United States. Few isolator standards exist and none of those that are in place have been developed with pharmacy compounding in mind. This guide is intended to provide an overview of isolators and assist individuals considering their use in purchasing, installation and commissioning issues.

CAG-002 - CETA Compounding Isolator Testing Guide

CURRENTLY BEING REVISED

The purpose of this document is to establish an industry-based minimum set of testing criteria appropriate for all Compounding Isolators used pursuant to USP Chapter 797. Compounding Isolators consist of Compounding Aseptic Isolators used for compounding sterile preparations and Compounding Aseptic Containment Isolators used for compounding sterile hazardous drug preparations in pharmacy applications. While this document gives general guidance or referenced guidance through relevant industry

documents, it is not the intention to set the specific acceptance criteria. It is the manufacturer's responsibility to determine exact testing procedures consistent with these guidelines and assign appropriate values pertaining to acceptance criteria that is consistent with user requirements. This guide has also been established to create a uniform approach for field certifiers to allow consistent and repeatable testing at all facilities.

CAG-003 - Certification of Sterile Compounding Facilities for USP Compliance

REVISED 2022

Certification of sterile compounding facilities and equipment must be performed in a consistent manner and in such a way that the tests are easily repeatable and well understood by the compounding facility and certification company. CAG-003 provides a basic understanding of concepts applicable to cleanroom and sterile equipment testing and certification. This guide, along with USP Chapters <797>, <800> and <825>, provide minimum acceptance criteria for many of the tests required for compliance to state boards of pharmacy regulations and other regulatory bodies. This guide explains the testing required and provides industry best practices where possible.

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CAG-004 - Biological Decontamination and Disinfection of Accessible Surfaces in Biosafety Cabinets

REVISED 2020

This CETA Application Guide serves as a guideline for the use of liquid chemical disinfectants to biologically disinfect (decontaminate) the readily accessible areas of Biological Safety Cabinets (BSCs). The guide serves as a general overview of these topics:

- The terms and definitions relating to surface disinfection.
- The precautions and safety measures that must be followed.
- When to surface decontaminate a BSC.
- The importance of Standard Operating Procedure (SOP) development.
- Remediation of biohazardous spills within the BSC.
- Different disinfection requirements for certifiers vs. users.
- A comparison of different microbes susceptibility to disinfectants.
- Characteristics of an ideal disinfectant.
- Factors concerning the use of disinfectants in BSCs.
- Tradeoffs (pros and cons) of different surface disinfectants.
- Supplemental information on disinfectants.

CAG-005 - Servicing Hazardous Drug Compounding Primary Engineering Controls

REVISED 2025

Many certification and service industry standards address technical practices specific to device testing applications. However, there is minimal guidance on PPE, risk assessments, decommissioning, and the steps to decontaminate properly when servicing containment primary engineering controls (C-PECs). This guide provides best practice safety considerations and precautions when performing service and repairs in hazardous drug (HD) environments. This guide

also provides information for assembling containment enclosures used to mitigate the migration of HD residue when performing work directly in hazardous drug contaminated areas.

CAG-006 - Procurement, Utilization, and Disposal of HEPA and ULPA Filters

REVISED 2023

High-efficiency particulate and ultra-low penetration air (HEPA and ULPA) filters are essential to the effective functionality of cleanrooms, clean spaces, and clean air devices. If these filters are not properly handled and maintained, the cleanliness of the environment served may be at risk of particulate contamination. This guide provides detail and best practices for the procurement, utilization, and disposal of HEPA and ULPA filters.

CAG-007 - Exhaust System Requirements of Class II Biosafety Cabinets

REVISED 2020

Class II Biosafety Cabinets (BSCs) are Primary Engineering Controls (PECs), that protect personnel, product, and the environment from biohazardous aerosols and volatile toxic chemicals appropriate for use in the BSC, after performing a chemical risk assessment. If these specialized pieces of equipment are connected to building exhaust systems, there are special requirements that set them apart from chemical fume hoods and other exhausted devices. This guide is intended to help the reader understand what those special system requirements are and how a BSC should be properly connected to a building exhaust system.

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CAG-008 - Certification Matrix for Sterile & Nonsterile USP Compounding Facilities

REVISED 2022

The need to have Sterile Compounding Facilities certified on a semi-annual basis has been dictated by current USP Guidelines. This Application Guide will serve as the baseline to have a Sterile Compounding Facility and its Primary Engineering Controls successfully certified in accordance with current ISO, USP, NSF and IEST standards. The requirements are laid out, test methods specified, acceptance criteria listed, and equipment needed to test described secondary engineering controls. Consideration should be taken to choose which testing to use based on Secondary and Primary Engineering Control Type.

CAG-009 - Viable Environmental Monitoring for Sterile Compounding Facilities

REVISED 2023

Viable environmental monitoring is an essential part of evaluating the state of microbial control in the sterile compounding environment. If environmental monitoring is not performed properly or frequently enough, it becomes difficult to understand the true microbial state of the tested environment. Without this understanding, patients could be at risk of receiving contaminated sterile compounded preparations. This guide provides detail on how to meet the minimum compounding standards, as well as best practice recommendations.

CAG-010 - CETA Application Guide for Informational Notes to Meet the NSF/ANSI 49:2010a Standard Requirements

REVISED 2011

The NSF/ANSI 49 Standard for Biosafety Cabinets: Design, Construction, Performance, and Field Certification had a significant number of changes and/or updates for the new 2010 release. The purpose of this document is to review the changes and provide some background and direction for compliance. In addition to the stated changes, a policy change has been implemented by NSF in the certification accreditation program to provide guidance to NSF accredited certifiers on how to apply these new standard changes. This policy change will be discussed in appendix A.

CAG-011 - Gloved Fingertip Testing for Sterile Compounding Personnel

REVISED 2023

Sterile compounding personnel pose the greatest risk to the microbial integrity of a compounded sterile preparation (CSP) through inherent bioburden and improper garbing practices. Gloved fingertip testing evaluates a compounder's competency in performing hand hygiene and garbing based on the facility's standard operating procedures.

CAG-013 – Media Fill Testing for Sterile Compounding Personnel

REVISED 2023

Sterile compounding personnel pose the greatest risk to the microbial integrity of a compounded sterile preparation (CSP) through inherent bioburden and improper or poor technique when preparing and handling CSPs. Media-fill testing evaluates compounding personnel's aseptic technique and ability to safely prepare CSPs for patients.

CAG-014 – Airflow Visualization Study

NEW 2022

Airflow visualization studies completed in sterile compounding facilities should be performed in a consistent manner and in such a way that the tests are easily repeatable and well understood by the compounding facility and certification company. CAG-014 provides guidance, methodology and industry best practices applicable to airflow visualization studies in primary engineering controls and cleanrooms.

CAG-015 – Testing of Pass-Throughs

NEW 2025

Pass-throughs can be an integral part of sterile compounding operations. Cleanroom designs may incorporate clean-air device pass-throughs, which are HEPA filtered, or static pass-throughs. Pass-throughs must function as intended and be properly maintained to ensure the cleanliness of the environment served is not at risk of particulate and microbial contamination. This guide provides testing procedures for clean-air device and static pass-throughs.

IN DEVELOPMENT

CAG-012 – Understanding Certification of Compounding Environments

CAG-016 – Testing of Hospital Operating Rooms